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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,916	10/10/2001	Peter M. Thule	US 1292/01 (VA)	4645

7590 09/15/2005

Law Office - Dinesh Agarwal, P.C.  
5350 Shawnee Raod, Suite 330  
Alexandria, VA 22312

EXAMINER

ANGELL, JON E

ART UNIT PAPER NUMBER

1635

DATE MAILED: 09/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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09/972,916

10/10/2001

Thule, P.

US 1292-01(VA)

EXAMINER

ANGELL

ART UNIT

PAPER

1635

20050912

DATE MAILED:

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**Commissioner for Patents**

Request for Information 37 CFR 1.105

It is noted that prosecution of the instant Application (09/972,916) has been re-opened. However, before prosecution can proceed, Applicant is requested to provide the following information under 37 CFR 1.105.

The claimed insulin regulator construct(s) appears to be described in the references previously cited as art under 35 U.S.C. 102(b), which are abstracts of public presentations presented by the Applicant more than one year prior to the effective filing date of the instant application. The cited references would be enabled if sequences of the vectors described in the cited references were adequately disclosed to the public. A printed publication can serve as a statutory bar under 35 U.S.C. 102(b) if the reference, combined with knowledge in the prior art, would enable one of ordinary skill in the art to reproduce the claimed insulin regulator construct. If one of ordinary skill in the art could obtain or reproduce the construct from a publicly available source, then a publication adequately describing the construct would be an enabling disclosure.

The cited publications disclose an insulin regulator construct that appears to be identical to the claimed insulin regulator construct. In fact, the constructs of the prior art and the instant specification include the Ad/(GIRE)3BP-1 2xfur construct. However, the cited publications do not disclose the actual insulin regulatory sequences of the construct. Therefore, a question remains as to the accessibility of the insulin regulatory sequences of the cited publications. A public disclosure of the insulin regulatory sequences, or possibly even a publicly disclosed description of the regulatory sequences could provide one of ordinary skill in the art enough information to reproduce the insulin regulatory constructs in view of the prior publications.

The Applicant and Assignee of this application are required under 37 CFR 1.105 to provide the following information that the Examiner has determined is reasonably necessary to the examination of this application. The information is required to determine if the claimed insulin regulatory sequences were publicly disclosed or described prior to the effective filing date of the instant application.

The information that is required to enter in the record is all information publicly disclosed in:

- (1) the presentation given by the Applicant at the 59th Annual Meeting of the American Diabetes Association, June 19-22, 1999;
- (2) the presentation given by the Applicant at the 2nd Annual Meeting of the American Society of Gene Therapy, June 9-13, 1999;
- (3) the presentation given by the Applicant at the 58th Annual Meeting of the American Diabetes Association, June 13-16, 1998; and,
- (4) Any other public disclosure by Applicant/Assignee of the GIRE/BP-1 constructs which was presented prior to the effective filing date of the instant application.

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✓ To be clear, the Applicant is required to submit the slides, overheads, poster information, or any other information necessary to determine if ANY sequence of the insulin regulator constructs, or description of the sequence, was publicly disclosed prior to the filing of the instant application.

It is reasonable to expect that Applicant or assignee can readily obtain the requested documents and information.

The fee and certification requirements of 37 CFR 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR 1.105 are subject to the fee and certification requirements of 37 CFR 1.97.

The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

This requirement is subject to the provisions of 37 CFR 1.134, 1.135 and 1.136 and has a shortened statutory period of 2 months. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

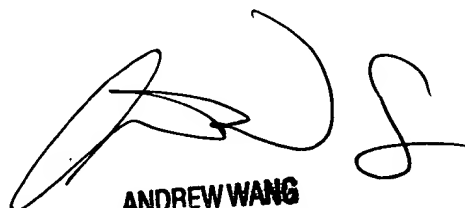
#### Future Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri 9:00 a.m. to 6:30 p.m., with first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system

Jon Eric Angell



**ANDREW WANG**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**